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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,811	07/10/2007	Jean-Guy Lehoux	2003390-0032 (ROBIC 01236	4922
24280 7590 01/27/2011 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER BLAND, LAYLA D	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 01/27/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.		Applicant(s)	
	10/584,811		LEHOUX ET AL.	
	Examiner		Art Unit	
	LAYLA BLAND		1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) 13-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/9/2010</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is a response to Applicant's amendment submitted December 9, 2010, wherein claims 7-8 and 12 are canceled. Claims 1-6, 9-11, and 13-19 are pending. Claims 13-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 30, 2010. Claims 1-6 and 9-11 are examined on the merits herein.

In view of the cancellation of claims 7-8 and 12, all rejections made with respect to those claims in the previous office action are withdrawn.

In view of Applicant's amendment submitted December 9, 2010, the rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite with respect to "several" is withdrawn.

In view of Applicant's amendment submitted December 9, 2010, the rejection of claims 1-6 and 9-12 under 35 U.S.C. 102(b) as being anticipated by Berthold is withdrawn. Berthold does not teach the use of a combination of two different salts for salting out.

In view of Applicant's amendment submitted December 9, 2010, the rejection of claims 1-6 and 9-12 under 35 U.S.C. 102(b) as being anticipated by Struszczyk is withdrawn. Struszczyk does not teach the use of a combination of two different salts for salting out.

In view of Applicant's amendment submitted December 9, 2010, the rejection of claims 1-6 and 9-12 under 35 U.S.C. 102(b) as being anticipated by Anderson is

withdrawn. Anderson does not teach the use of a combination of two different salts for salting out.

In view of Applicant's amendment submitted December 9, 2010, the rejection of claims 1-6 and 9-12 under 35 U.S.C. 102(b) as being anticipated by Sannan is withdrawn. Applicant's arguments are persuasive. Although Sannan teaches the use of two different salts, Sannan prepares a carbamoyl chitosan derivative. The instant specification, paragraph [0025], states that the precipitated chitosan is one wherein properties such as charge and molecular size are identical to the native chitosan. Thus, the claims are not interpreted to encompass forming aqueous compositions comprising chitosan derivatives.

The rejection of claims 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sannan et al. (US 4,267,313, May 12, 1981) in view of Berthold is withdrawn for the reasons set forth above.

The following new rejection was necessitated by applicant's amendment submitted December 9, 2010, wherein the scope of claim 10 was changed to encompass polymers having a molecular weight of at least about 7 kDa.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 11 recites the limitation "molecular weight of at least about 7 kDa." The recitation "molecular weight of at least about 7 kDa" lacks of adequate written description since this recitation reads literally on any chitosan polymers having molecular weight of more than 7 kDa, with no upper limit.

The specification and original claims provide support chitosan polymers of molecular weights approximating 7 kDa to hundreds of kDa, including examples at 240 kDa or 300 cps, but the specification as originally filed does not provide support for compositions having molecular weight of at least 7 kDa with no upper limit. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), regarding a corresponding new claim limitation with no upper limit. See also *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000). Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

The following rejection of record is maintained and modified to include the Tan reference:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mallon et al. (US 5,733,462, March 31, 2998, of record) in view of Singla et al. (Journal of Pharmacy and Pharmacology 2001, 53:1047-1067, of record) and Tan (CN 1364815A, August 21 2002, PTO-1449).

Mallon teaches methods for precipitating cationic polymers using salt solutions [see abstract]. The process comprises mixing, in any order, water, at least one cationic water-soluble polymer, an effective amount of kosmotropic salt, and an effective amount

of chaotropic salt to form an aqueous composition comprising at least one precipitated cationic water-soluble polymer [column 5, lines 14-32]. Water-soluble cationic polymers are precipitated more effectively by a combination of chaotropic and kosmotropic salts than by either salt alone [column 8, lines 27-42]. Exemplified salt combinations include ammonium sulfate and sodium thiocyanate or sodium sulfate and sodium thiocyanate [Figures 1 and 2].

Mallon teaches precipitation of cationic polymers, but does not teach precipitation of chitosan in particular.

Singla teaches that chitosan is a cationic polymer which is soluble at acidic pH [page 1049, Table 3]. A high electrolyte concentration results in a salting-out effect leading to precipitation of chitosan from the solution [page 1049, first full paragraph].

Tan teaches a method for producing chitosan, which includes salting out with sodium sulfate, potassium sulfate, ammonium sulfate, sodium chloride, potassium chloride, or magnesium chloride [claim 6].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out the precipitation or salting-out of chitosan using a combination of kosmotropic and chaotropic salt. Mallon teaches that precipitation of cationic polymers is more effective using the combination of a kosmotropic and a chaotropic salt than either alone. Chitosan is a cationic polymer which is precipitated or salted-out from solution using salts such as sodium sulfate or ammonium sulfate. The skilled artisan would precipitate chitosan using a combination of salts because Mallon teaches that a combination is more effective than a single salt. Mallon's examples

include ammonium sulfate and sodium thiocyanate or sodium sulfate and sodium thiocyanate and precipitation of chitosan using sodium sulfate alone is known, as taught by Tan. The skilled artisan would expect that the combination of ammonium sulfate and sodium thiocyanate or sodium sulfate and sodium thiocyanate would effectively precipitate chitosan because sodium sulfate is already known for that purpose and Mallon teaches that addition of another salt such as sodium thiocyanate would give a more effective precipitation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on December 9, 2010 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623